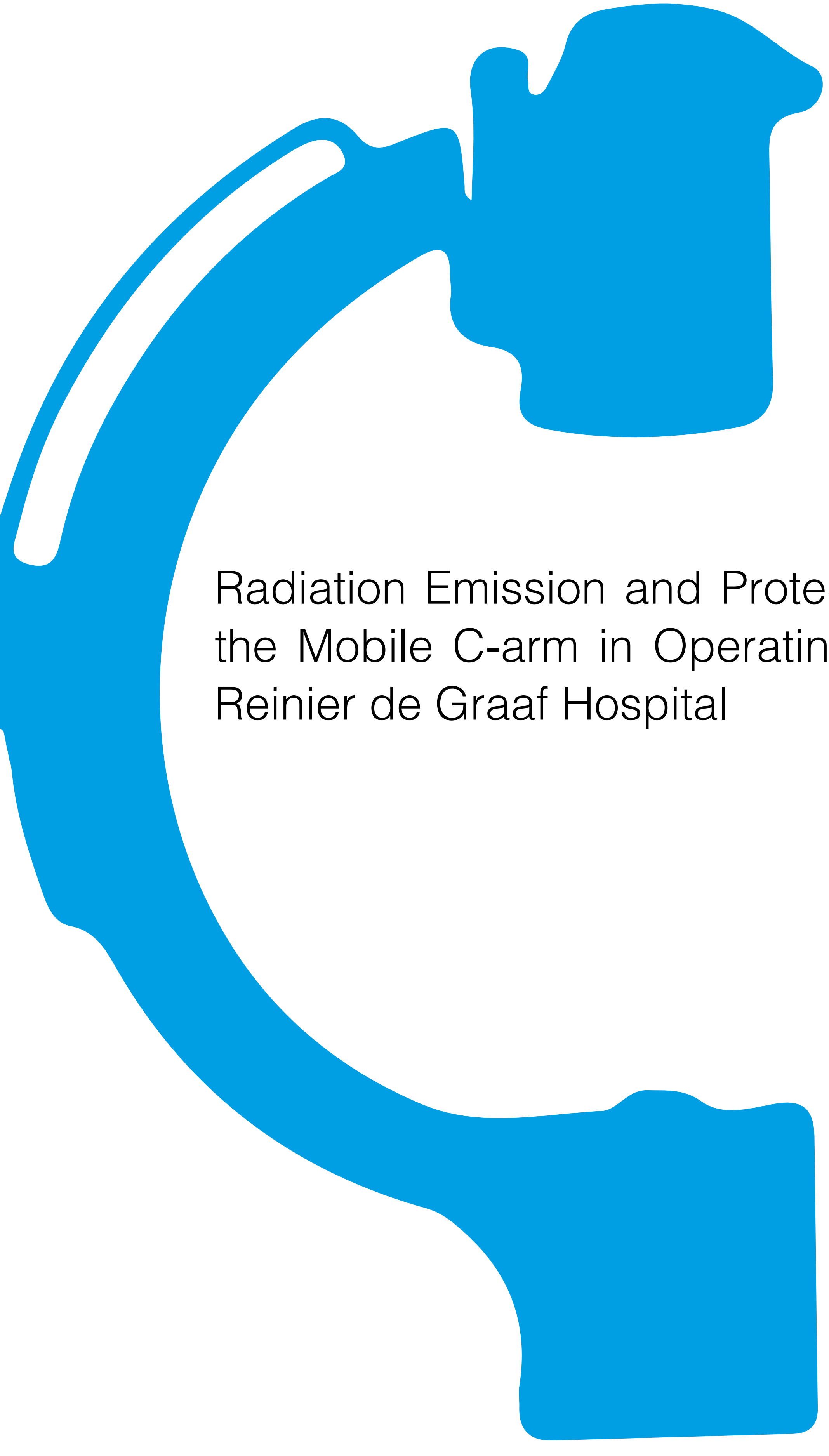

Radiation Emission and Protection Regarding the Mobile C-arm in Operating Rooms of the Reinier de Graaf Hospital

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Radiation Emission and Protection regarding the Mobile C-arm in Operating Rooms of the Reinier de Graaf Hospital

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Chapter 1

Abstract

Objectives The goal of this study was to investigate whether mobile C-arms are being optimally used, securing the safety of staff members in operating rooms of the Reinier de Graaf hospital (RDGG). Mobile C-arm use is evaluated in terms of radiation emission and radiation exposure, staff communication and procedural aspects.
Methods The current use of the mobile C-arms was evaluated based on radiation emission data obtained from the X-ray devices and systematic observations in the operating room. From the X-ray devices, the number of exposures, fluoroscopy time, Dose Area Product (DAP) and Air Kerma (AK) values were obtained for trauma, orthopedic and vascular procedures that took place in 2019 and 2020 (until 16-3-2020). These values were visualized and the correlation between the variables was investigated. Observations took place in the operating rooms of the RDGG to evaluate staff actions, staff communication, C-arm utilization and time courses. Finally, the results from previously performed experiments into staff exposure have been evaluated. For these experiments, DoseAware badges were used to measure the dose received by staff members real time during Endovascular Aneurysm Repair (EVAR).
Results Radiation emission data of trauma procedures showed high variability and relatively low patient dose compared to vascular surgery. A positive correlation was found between the number of exposures, fluoroscopy time, DAP and AK. The strongest correlation was found between DAP and AK. During observations, the staff has indicated to be aware of how to keep radiation exposure as low as reasonably possible, however in practice, few actions are being undertaken to minimize the dose. Also, communication between surgeon and C-arm controller and the experience of the C-arm controller and surgeon seem to have significant influence on the radiation use and operating time. Mainly lack of experience of the C-arm controller has shown to affect the number of exposures and process flow. The heavy and large design of the C-arm also complicates communication and positioning. Finally, DoseAware experiments showed that during EVAR procedures, the anesthesiologist and C-arm controller receive a significant dose which can be avoided.
Conclusions From available data, it can be concluded that the C-arm is currently not optimally used in the Reinier de Graaf hospital. The dose received by staff members is higher than necessary in order to provide good patient care. Differences in dose received for different types of surgery that make use of the same fluoroscopy time can be appointed to the size of body parts that are operated and the use of metal. In order to optimize the use of the mobile C-arm, the number of exposures can be decreased by education of C-arm controllers and communication improvement. A redesign of the C-arm could make communicating and positioning of the C-arm easier. Also, staff awareness should lead to actions in limiting exposure by shielding and taking distance. Finally, the current system concerning C-arm controller allocation to procedures should be revised. In order to enable future improvements, radiation and procedural data should be stored more specifically and continuously.

Contents

[1] Hand, wrist, ankle and foot are assigned to be extremities in this study.

Chapter 2

Introduction

Technological developments are accelerating in order to improve the quality of health care globally. The goal is to provide efficient, high quality care to patients while minimizing the costs [1][2]. High quality care is often primarily associated with patient safety; patient mortality and morbidity are the most used outcome measures to evaluate quality of care [2][3]. However, quality can not only be assessed based on patient safety when risks for caregivers are involved. Caregivers regularly encounter risky situations, for example when working with highly infectious diseases or radiation exposure. This study investigates the optimal use of the mobile C-arm in operating rooms of the Reinier de Graaf hospital (Delft, The Netherlands), focusing on radiation safety of staff members that work with the X-ray devices.

Mobile X-ray devices are currently used in the operating room to visualize human tissue during operations. In orthopedic, trauma, urological and vascular surgery, X-rays are important to obtain sufficient visual information whilst performing surgery in a minimally invasive way. The settings of the X-ray tube differ per type of operation; orthopedic and trauma procedures focus mostly on bone structures and metal implants while in urological and vascular procedures, mainly soft tissue is visualized. X-rays can be dangerous for humans because of the ionizing properties of radiation, which induce mutations in DNA or lead to cell death. To prevent harmful effects from occurring, the exposure of the human body to radiation should be minimized [4]. Additional information on the working principle of the C-arm and the harmful effects of radiation can be found in Appendix B.

It is important that all people in the operating room (OR) are aware of the risks of ionizing radiation and know how to minimize exposure to patient and staff members. The ALARA principle is designed to keep the radiation dose to patient and surroundings As Low As Reasonably Achievable (ALARA) and should be followed at all times. Whether actions undertaken to minimize the dose are reasonable is mainly determined by economic and social factors. Four main actions can be undertaken to reduce the received dose; taking distance to the source, the use of shielding, limiting the screening time and tuning the tube settings as much as possible [4]. These measures are taken in the operating room to protect the patient and staff from harmful effects of radiation.

Radiation exposure and protection for operating staff is a widely investigated topic, mainly studying the effects of shielding and distancing from the source [5][6]. Research groups have mapped the X-rays scatter throughout the operating room using dosimeters to measure radiation. Most studies were performed using phantoms to mimic human body properties while some used patients [7] [8]. Results showed that different body parts of the surgeon received varying radiation doses, and the location of the surgeon in the operating room had large impact on the received dose. Also, the angle of the C-arm and patient angle have shown to influence radiation scattering [9]. So far, research groups have studied the use of X-rays and the staff exposure for specific procedures, but few research has been carried out into the use of mobile C-arms in daily practice in general hospitals.

The goal of this study was to investigate whether mobile C-arms are being optimally used, securing the safety of staff members in operating rooms of the Reinier de Graaf hospital (RDGG). Mobile C-arm use is evaluated in terms of radiation emission and radiation exposure, staff communication and procedural aspects.

The C-arm is optimally used if a sufficient amount of fluoroscopy is used to provide best possible patient care whilst keeping the radiation exposure to patient and staff as low as possible.

When mapping X-ray emission, we look at the radiation that is currently used for different types of procedures and whether patterns can be found among these procedures. In order to map X-ray emission, we analyse radiation data acquired from the mobile C-arms of the hospital. These data provide information on the estimated patient exposure per procedure. Besides this, we investigate whether radiation protection is secured by operating staff. During observations in the operating room, the main question is whether members are aware of the risks and guidelines concerning radiation protection, and whether they act on this knowledge. Results from previously performed experiments provide insights into the dose received by different staff members during vascular surgery. Finally, we determine whether additional actions can be undertaken in order to minimize the dose received by OR staff.

Chapter 3

Methods

When investigating the optimization of mobile C-arm use, the first step is to map the current use of X-rays. Based on those results, suggestions can be made on how to reduce radiation exposure while maintaining/improving the quality of patient treatment. Initially, experiments were planned in the operating rooms of the Reinier de Graaf hospital (RDGG) in Delft, the Netherlands, mapping real time radiation exposure to surgical staff during surgical procedures (see details in Appendix F). However, due to external circumstances [1], it wasn't possible to perform the experiments as planned in the hospital.

Despite this, data were obtained to map the current use of the mobile C-arm in terms of radiation emission from the C-arm, radiation exposure, staff communication and procedural aspects. The first data source consists of radiation emission data from a collective file. These radiation data are sent from the C-arm to the collective data file after surgical procedures. The second source includes observation data from a number of procedures that were attended. Thirdly, radiation exposure data were obtained from previous experiments carried out by clinical physicians of the RDGG. Based on these 3 sources of information it was possible to get a picture of the current situation. This section further elaborates on the 3 data acquisition methods.

3.1 Radiation Emission

Radiation data were collected from the Veradius Unity mobile C-arm, developed by Philips (Eindhoven, the Netherlands). The mobile C-arm emits X-rays in a bundle that enters the human body where different tissue types attenuate X-rays differently, which is detected by the C-arm detector. Images are shown on a monitor that is connected to the C-arm during surgery. More information on the working principle of the C-arm can be found in Appendix B. All data were made anonymous by removing patient specific information. From the remaining data, the following information could be retracted:

- The exam name, specifying the body part that was screened. All exam names can be found in Appendix C, Table C.2.
- Number of exposures (also referred to as 'runs'). Every activation of the X-ray tube, independently of the duration of the screening, was counted as an exposure. To acquire one image of the body, the fluoroscopy duration is around 0,5 to 1 second per exposure. When screening for a longer time, which is often necessary in vascular surgery, a moving image can be obtained and screening duration can take up to 250 seconds per exposure. Moving images are registered as one exposure.
- Total fluoroscopy time in seconds. This measurement represents the sum of the durations of all screenings.

[1] Measures concerning COVID-19 prohibited all hospital entries with exception for direct care providers. The planned experiments could therefore not be performed.

- Total calibrated Air Kerma (AK) value in mGy. The AK value represents the dose received by the patient at a reference point, 30cm from the detector. Important to note is that the distance between the patient and X-ray tube varied and was not always 30 cm.
- Total calibrated Dose Area Product (DAP) in Gy cm^2. The DAP value is an output measurement of the total amount of radiation delivered to the patient, defined as the absorbed dose multiplied by the area that is irradiated. The level of irradiation is thus independent of the location of the patient relative to the X-ray source.

Filed data from mobile C-arms were reviewed to map radiation emission for different types of procedures. For this study, hand/wrist and ankle/foot procedures were assumed to be trauma procedures with equal C-arm settings and therefore could be summarized. In this report, hand and wrist will be referred to as 'hand', and foot and ankle will be referred to as 'foot'. It is important to note that these procedures, although all trauma surgery performed on the same body part, vary a lot dependent on the type of fracture and patient characteristics. Table 3.1 shows which procedure types from the C-arm data file were included for data analysis of hand, foot, hip and vascular surgery.

The types of surgeries were chosen because they occur most frequently in the RDGG and thus have large sample sizes. In total, radiation emission data were analysed from 1528 procedures performed in 2019 (1279 procedures) and 2020 until 16-03-2020 (249 procedures) in the RDGG. These 1528 procedures contain all operations performed using a C-arm, including 107 hand/wrist, 120 vascular, 149 foot and 780 hip procedures.

The variability of the fluoroscopy time, the number of exposures, DAP and AK values was mapped for foot, hand, hip and vascular surgery. The variability of a data set provides information about the similarity of the values within the data set; low variability means that the values within a data set are very similar, high variability means that the data are spread. In this case, low variability indicates that the radiation use for operations within the same procedure type is very similar, high variability means that the use of radiation varies for different cases within the same procedure type. Common measures of variability include the range, variance, standard deviation and CV. In this study, the range is defined as the difference between the largest and smallest value. The CV (coefficient of variation) is a relative measure of variability, obtained by dividing the standard deviation by the mean.

Besides this, the irradiation of hand, foot, hip and vascular surgery were individually compared to the rest of the filed C-arm data. In this way, we could investigate e.g. fluoroscopy time of vascular surgery relative to the fluoroscopy of other types of surgery. Data were visualized for the above mentioned variables of hand, foot, hip or vascular surgery and were plotted against the same variable data derived from all other procedures that utilized a C-arm. Hereby, data from all other procedures include all data from the C-arm data file, including urology procedures etc. This means that in each plot, all procedures performed in 2019 and 2020 (until 16-3-2020) are represented. Table 3.1 shows which exam names are included in the analysis of hand, foot, hip and vascular surgery. All exam names present in the C-arm data file can be found in Appendix C, table C.2.

Finally, the correlation between the 4 variables mentioned above (the number of exposures, fluoroscopy time, total AK and total DAP) was measured. In this way the relation between all combinations of variables could be investigated.

The data were normalized and Spearman correlation measured the strength and direction of the monotonic relation between the variables. Spearman correlation was used instead of Pearson correlation because most data were not normally distributed and Spearman correlation does not carry any assumptions about the distribution of the data. Output R indicates the strength of the correlation between 2 variables, p indicates the significance based on sample size. The significance level is defined as $p < 0{,}05$. The R value is always between -1 and 1, where R= 0 indicates no association between ranks, R=-1 a perfect negative association and R=1 a perfect positive association. According to Cohen's standard, R values between 0.3 and 0.49 represent a medium association and R values of 0.5 and above represent a strong correlation [10].

Table 3.1: Data from the C-arm data file that were included when looking specifically at hand, foot, hip or vascular surgery.

Data name	Original exam name	English translation exam name
Hand	Doorlichting hand links	Screening left hand
	Doorlichting hand rechts	Screening right hand
	Doorlichting pols links	Screening left wrist
	Doorlichting pols rechts	Screening right wrist
Foot	Doorlichting voet links	Screening left foot
	Doorlichting voet rechts	Screening right foot
	Doorlichting enkel links	Screening left ankle
	Doorlichting enkel rechts	Screening right ankle
Hip	Doorlichting bekken/heup	Screening pelvis/hip
	Skelet- Heup/been	Skeleton hip/leg
Vascular	Aortastentgraft op OK	Aortic stent graft OR
	Arteriografie op OK	Arteriography OR
	Cardio-Pacemaker	Cardio-Pacemaker
	PTA occlusie femoraal	PTA for femoral occlusion
	PTA stenose coeliacus	PTA for celiac artery stenosis
	Stent occlus. iliacaal	Stent occlusion iliac artery
	Vasculair-Abdominaal	Vascular-Abdominal
	Vasculair-Arm	Vascular-Arm
	Vasculair-Been	Vascular-Leg
	Vasculair-Cerebraal	Vascular-Cerebral

3.2 Observations Operating Room

Observations took place during routine surgery in operating rooms of the Reinier de Graaf hospital in Delft (RDGG), the Netherlands. The goal of the observations was to map the use of the C-arm for standard procedures in the operating room, define roles of the staff and detect bottlenecks and factors that induce the occurrence of complications. During the procedures, the observer was positioned at the side of the OR, registering movements and actions of staff members and the mobile C-arm (Philips Veradius Unity). Table 3.2 shows the subjects and topics of observation during operation. As can be seen in the table, the observations were focused on staff, C-arm and overall process characteristics. For each of these subjects, multiple topics were analyzed such as the main location of a staff member, the movements made and communication among staff.

The C-arm variable data (fluoroscopy time, number of exposures, AK and DAP) from observed procedures were copied from the C-arm monitor after the procedure or retrieved from the collective data file. Radiation data were visualized in MATLAB R2017. Due to the small sample sizes, a boxplot would provide an unreliable representation of the data, so individual value plots were made to visualize the number of exposures, fluoroscopy time, Air Kerma and DAP.

Inclusion of operations

Criteria for the procedure to be included in this study were the use of a C-arm and to be carried out by the trauma, orthopedic, neurosurgical or vascular department. For attended procedures that didn't require X-ray screening, the

Table 3.2: Subjects and topics of observation during surgery.

Subject	Observation topic	Explanation
Staff	Presence	Staff members and other people present in the OR during surgery
	Location & Movements	The location and movements of staff members during the operation
	Workload	The workload of staff members during the operation
	Distancing	Distance to the radiation source during screening
	Shielding	Protective wear or other shielding methods
	Experience/skills	The skills from operating staff, often highly correlated with experience
	Communication	Communication between staff members concerning the operation
	Opinion	Staff was asked for their opinion on the OR processes, C-arm use and communication
C-arm	Set up	Planning and preparation of the C-arm
	Location & Movements	Location and movement of the C-arm relative to the patient during surgery
	Radiation use	Tube settings, time points of screening and amount of images made during surgery
	Radiation data	Acquisition of total fluoroscopy time and total AK value from C-arm
Process	Time course	Time points of events and operation phases
	Patient factors	Patient factors that influence radiation use
	Delays & complications	Complications concerning logistics, instruments and staff members

staff and process observations did contribute to the findings reported in Appendix E.

The observed hand and wrist trauma operations were bundled to one type of surgery since the C-arm settings are mostly equal and their anatomical position is very close. The same goes for foot and ankle procedures. Total hip prostheses (THP) are part of the orthopedic surgery department, hand and foot fractures are mostly treated by the trauma surgery department.

3.3 Data DoseAware experiments

Philips developed a real time dosimeter called DoseAware (RaySafeTM, Billdal, Sweden, distributed by Philips, Eindhoven, The Netherlands) with the aim of increasing awareness of the received dose by exposed workers. The DoseAware badge is worn upon the lead apron, measuring the individual radiation exposure. These data are sent wireless to a display that shows the received dose real time to the operating personnel.
Medical physicists Jip Pluim and Vincent Verhoeven measured radiation dose received by different staff members in the operating room during surgery, using the DoseAware system (Philips, Eindhoven). The surgeon, assisting staff and the C-arm operator were equipped with the dosimeter during an EVAR (endovascular aneurysm repair) procedure. The goal of these experiments was to establish the relative radiation exposure of different persons within the OR of the RDGG. The dose rate (mSv/h) and accumulated dose were registered each second for 8 badges worn by the anesthesiologist (1), C-arm operator (2), sterile laboratory technician (3), radiologist (4), Medtronic employee (5), two OR assistants (6,8) and the surgeon (7) (see Figure 3.1). The radiation dose per point in time and the total dose (in μSv) were registered for all badges. However, the phase of surgery and actions of staff members at those time points were not documented, making it hard to draw conclusions from the radiation data. Due to the mentioned circumstances the experiments could not be repeated and extended, but some information has been retracted from the previous experiments.

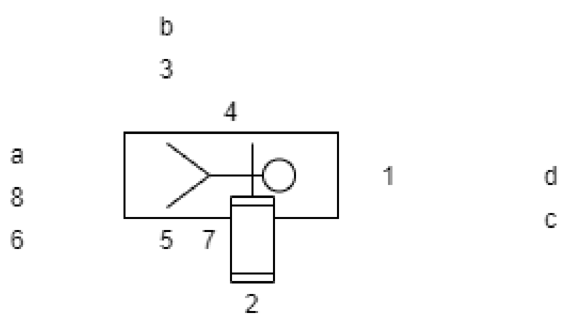

Figure 3.1: Positions of staff members during EVAR procedure. 1 = anesthesiologist, 2 = C-arm controller, 3 = lab. technician, 4 = radiologist, 5 = Medtronic employee, 6 = circulator, 7 = surgeon, 8 = circulator, a = lab. technician, b = surgical assistant, c = clinical physician, d = Philips employee.

Chapter 4

Results

In this chapter, the findings from 3 data sources are presented. First, the radiation data obtained from the C-arm were visualized and analyzed. Secondly, the findings from observations were reported, categorized according to the subjects and objects stated in Table 3.2. Thirdly, results from the previously performed experiments during an EVAR procedure in the RDGG are presented. Fourthly, a discussion reflects on the data acquisition.

4.1 Radiation Emission Data Analysis

Data were obtained from the mobile C-arms that are used for fluoroscopic screening in operating rooms of the Reinier de Graaf Hospital. After each procedure, radiation data from the mobile C-arm are sent to the confidential patient files and a collective C-arm data file where they are saved under exam name and date. For this study, data were retrieved from the collective data file.

4.1.1 Initial findings

For all exam names starting with "Doorlichting" (screening), 2 notation variations occurred in the data file. Knee screening for example, was registered under both "Doorlichting knie links" and "Doorlichting knie links Doorlichting knie links" (see Appendix C, Table C.1). The registered exam name depends on which C-arm sends the data. After surgery, the C-arm data are registered in a collective file that contains data for all procedures. Selected images and the patient dose are sent to the patient file.

From the examined C-arm data, it was noticed that not all information is sent from the C-arm to the collective file; some procedures have no registered data and for some procedures the data are incomplete or possibly incorrect. The possible incorrectness was deduced from a difference between values that were directly obtained from the C-arm and values in the collective file. Besides this, the exam names in the collective data file describe the body part of interest, but give no specification of the operation was given (all exam names can be found in Appendix C, Table C.2). Since multiple types of operations can be performed on the same body parts, this complicates data analysis.

4.1.2 C-arm data analysis

Table 4.1 shows the variability of the variables for each procedure type. The DAP is generally in a different (higher) order of magnitude for vascular procedures than for hand or foot procedures, which is compensated for in the CV value. Table 4.1 shows that the number of exposures is the least fluctuating variable compared to fluoroscopy time, DAP and AK value. The similarity in CV between DAP and AK values confirms the expectation that the measures are proportional to each other. Finally, the high variability in DAP and AK values for hip surgery is remarkable (CV is 2.15 and 2.14 for DAP and AK respectively).

Irradiation for different types of surgery was also compared by visualizing the number of exposures, fluoroscopy time, DAP and AK data for a procedure type relative to the others.

Table 4.1: Variability measures are calculated for foot, hand, hip and vascular surgical procedures performed in the Reinier de Graaf hospital in 2019 and 2020 (until 16-3-2020).

Variable	**Procedure type**	**Std**	**Variance**	**Coefficient of Variation**	**Range**
Fluoroscopy time	Foot	54.1038	2.9272e+03	1.3076	395.1600
	Hand	51.1880	2.6202e+03	1.1765	324.3800
	Hip	59.0696	3.4892e+03	1.4584	855.2500
	Vascular	836.6358	6.9996e+05	0.8520	4.3378e+03
Number of exposures	Foot	32.0886	1.0297e+03	0.8635	209
	Hand	31.5682	996.5506	0.8313	156
	Hip	50.0038	2.5004e+03	0.9837	476
	Vascular	54.5813	2.9791e+03	0.7068	257
Dose Area Product (DAP)	Foot	0.1322	0.0175	1.7173	1.0100
	Hand	0.0548	0.0030	1.5492	0.3700
	Hip	1.3936	1.9421	2.1495	30.3000
	Vascular	55.8287	3.1168e+03	1.7818	550.2800
Air Kerma (AK)	Foot	0.5107	0.2608	1.6322	3.9900
	Hand	0.3497	0.1223	1.5983	2.5600
	Hip	5.2515	27.5781	2.1434	100.8400
	Vascular	197.6143	3.9051e+04	1.6582	1.8451e+03

Figure 4.1 visualizes all data and makes a distinction between hand procedures in blue and all other operations that make use of fluoroscopy in red. It is shown that especially the DAP and AK value of hand surgery are very low compared to DAP and AK of other procedures. The number of runs is more similar to other operations. Compared to the number of runs, fluoroscopy time is relatively low. Also, vascular procedures seem to be the sole cause of the large peak in fluoroscopy time (see Figure 4.3), thereby overshadowing differences between other procedures. Similar results can be seen in Figure 4.2 that exposes foot surgery relative to the other procedures; relatively low fluoroscopy time, DAP and AK value compared to the number of exposures.

Figure 4.3 makes a distinction between vascular procedures in blue and all other operations that make use of fluoroscopy in red. It can be seen that the number of runs is relatively low but the fluoroscopy time, DAP and AK values are high compared to the other procedures. The number of exposures is relatively low but the duration of an exposure is very long: the mean vascular fluoroscopy time is 981,9 seconds and the mean hand fluoroscopy time is 43,5 seconds whereas the mean number of runs is approximately twice as high for vascular surgery (vascular surgery mean= 77,2 runs, hand surgery mean= 38,0).

Figure 4.4 shows that the number of runs needed in hip surgery is comparable to those of other procedure types, the fluoroscopy time is relatively low. The DAP and AK value are significantly larger than for foot and hand operations. Despite this, these dose measurements are still relatively low compared to some other procedures and Figure 4.1 and Figure 4.2 show that extremities also bring down DAP and AK averages. This raises the expectation that mainly vascular procedures are responsible for the high DAP and AK values. When comparing the blue line in Figure 4.3, indicating DAP and AK of vascular procedures, to the red lines in the other figures, indicating DAP and AK of

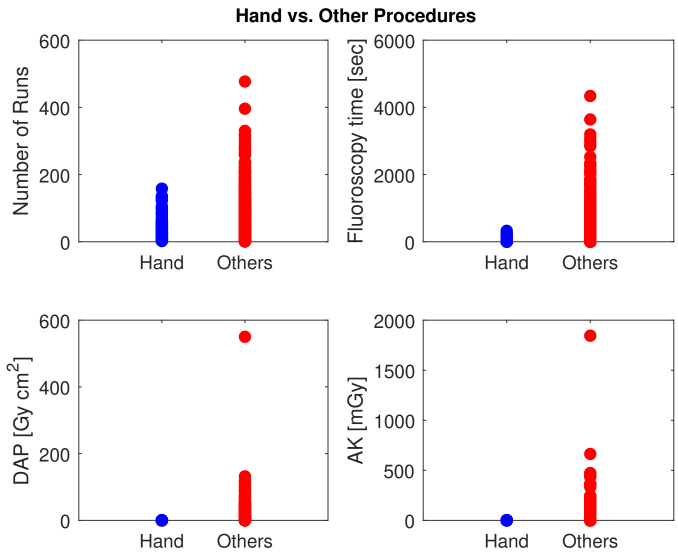

Figure 4.1: The radiation emission of hand surgery in terms of runs, fluoroscopy time, DAP and AK value, compared to radiation emission of all other procedures merged.

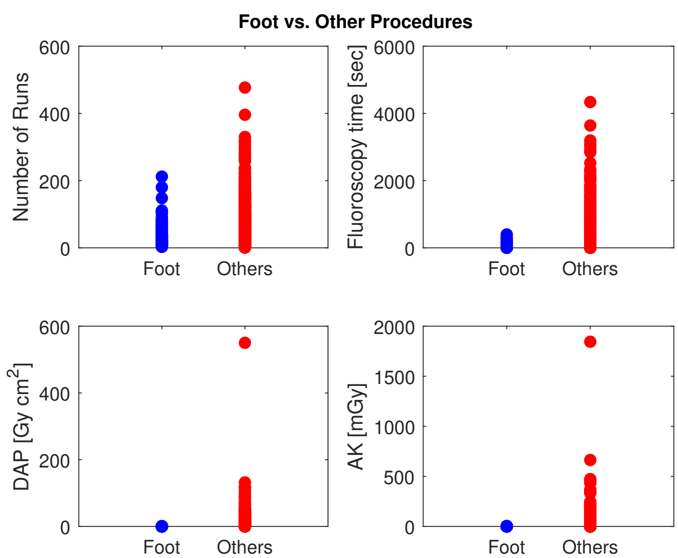

Figure 4.2: The radiation emission of foot surgery in terms of runs, fluoroscopy time, DAP and AK value, compared to radiation emission of all other procedures merged.

all other procedures including vascular surgery, these lines seem to match. Especially the top part of the graph showing the higher values seems to correspond between the figures. These observations support the expectation that vascular surgery is responsible for high DAP and AK values.

Besides comparison of the spreading, the relation between the variables was evaluated. Spearman's Rank Correlation Coefficient R and probability p are calculated for variable combinations of all procedures registered in the data file. The diagonal plots show the distribution of the variables in histograms. Looking at the relation of the

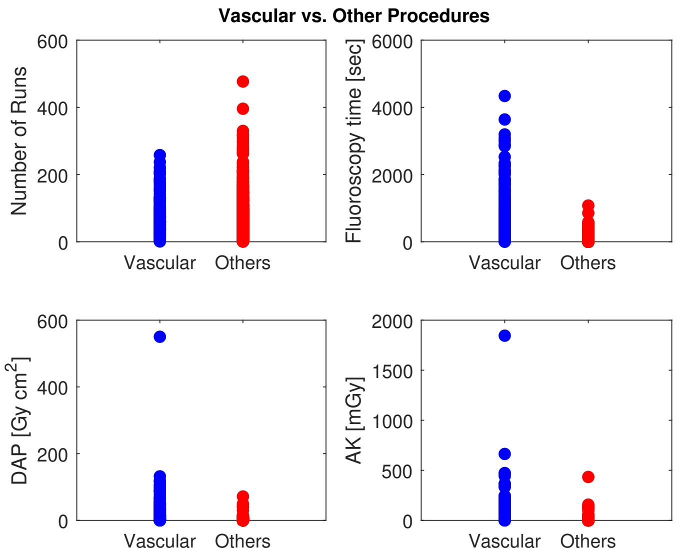

Figure 4.3: The radiation emission of vascular surgery in terms of runs, fluoroscopy time, DAP and AK value, compared to radiation emission of all other procedures merged.

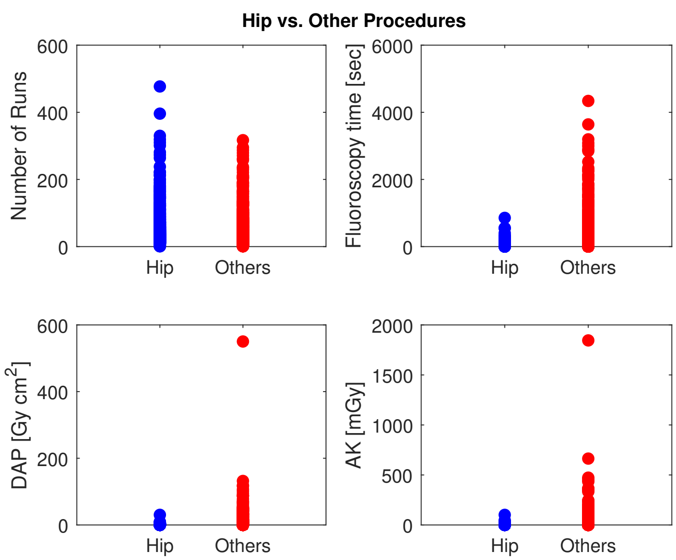

Figure 4.4: The radiation emission of hip surgery in terms of runs, fluoroscopy time, DAP and AK value, compared to radiation emission of all other procedures merged.

variables in practice, is was expected that all variable combinations were positively correlated to a greater or lesser extent.

The Spearman correlation plot (Figure 4.5) confirms the suspicion based on Table 4.1 that DAP and AK value are strongly correlated (R=0.99, p $<$ 0.001). The amount of exposures (runs) and fluoroscopy time (time) show a slightly lower value for R (R= 0.85, p $<$ 0.001) but still significant according to Cohen's standard. Despite this, the graphs comparing fluoroscopy time and runs show a less good fit than would be expected from the R value. Two point clouds are distinguished: in the left column ('runs') the line is drawn between the point clouds, whilst in the adjacent column ('time') the line is drawn through the spread point cloud. Looking at the two point clouds, the line is a bad fit and not representative for the correlation between the variables. DAP and AK both have relatively weak but still positive correlations to the number of exposures and the fluoroscopy time. AK values show better correlation to fluoroscopy time and number of exposures than DAP values. For all correlations shown in the plot, $p< 0.05$, indicating significant correlation.

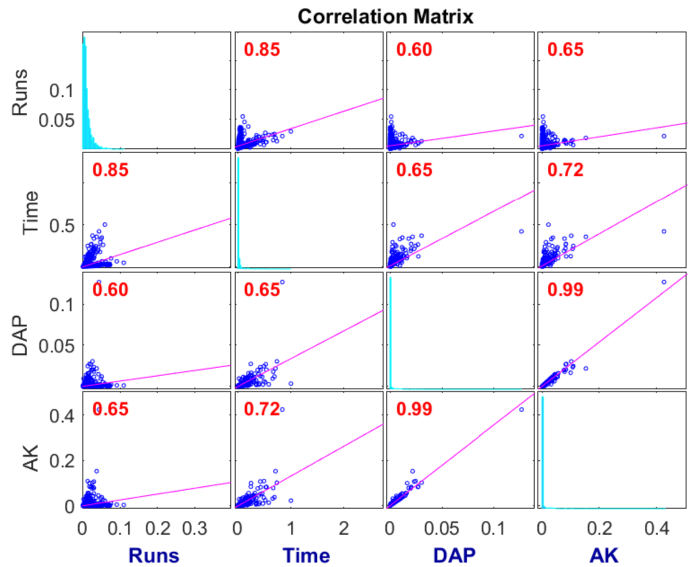

Figure 4.5: Correlation plot showing correlation between the number of exposures, fluoroscopy time, DAP and AK for all operations using a mobile C-arm. The R value is shown in red. The diagonal plots (e.g. Runs - Runs) show variable distribution in histograms.

4.2 Observations Operating Room

In the Reinier de Graaf hospital, 46 Procedures were attended, of which 34 used a C-arm. An overview of the attended procedures can be seen in Figure 4.6 and Table 4.2 describes the observed procedures more specifically. The most frequently attended procedures are elaborated on in Appendix D.

The distance between the patient and the X-ray tube per procedure and within procedures. Optimally, the patient was positioned as close to the image intensifier as possible to minimize the dose received by the patient.

The amount of radiation received by the staff is dependent on the radiation that is emitted from the X-ray tube and the protective measures that are being taken by the staff. In this study, we investigated whether these are both kept as low as possible in the operating room of the RDGG. For all observed procedures, the subjects listed in Table 3.2 have been investigated and results were registered.

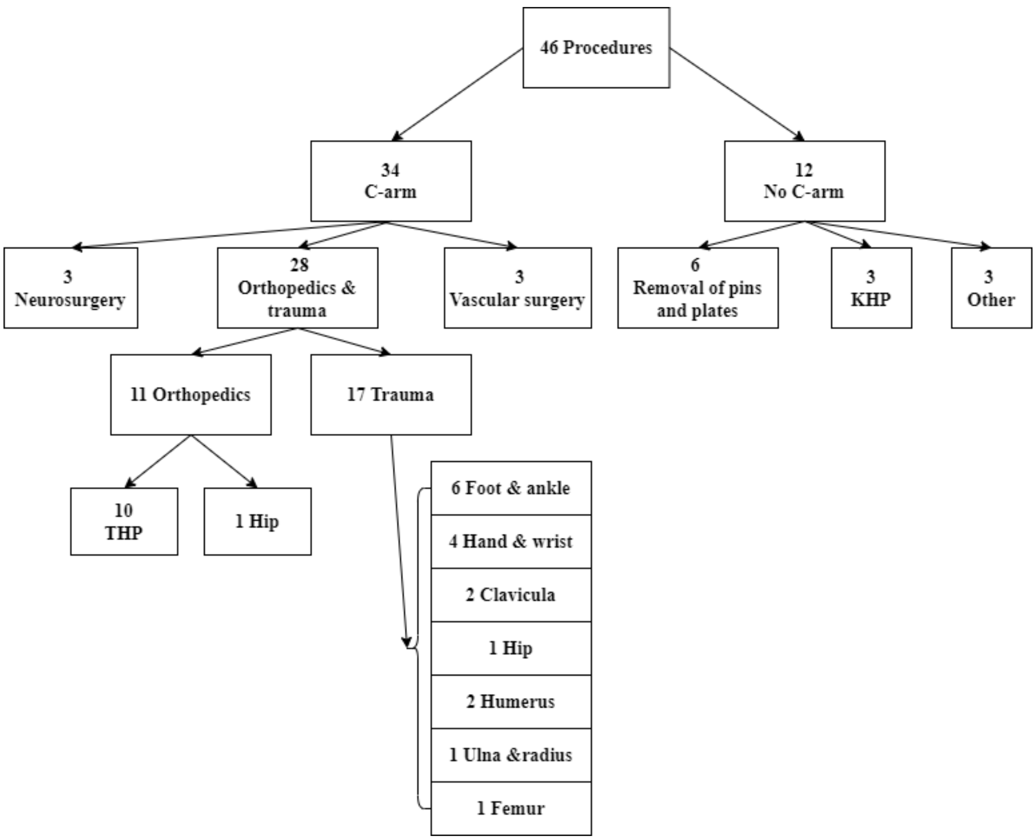

Figure 4.6: Overview of observed procedures in the RDGG, sorted based on whether a C-arm was used. KHP= short-stem hemiarthroplasty (kop hals prothese).THP= total hip replacement (totale heup prosthese).

4.2.1 Staff

Presence Surgery was performed by teams that varied in composition, changing people not only between procedures but also during the operation. Figure 4.7 shows the general set up of most trauma and orthopedic surgery and main communication lines between people that are normally involved in surgery. The surgeon and assisting surgeon work together while being provided with instruments by the surgical assistant. Surgeons and the surgical assistant communicate with the circulator about necessary instruments and implant materials. Anesthesiology employees communicate with the patient (if not under general anesthesia) and with the surgeon about the patients status. Additional observers such as medial students, external observers or assistants in training are often present in the

Table 4.2: Description of the observed procedures in the operating room of the RDGG that made use of a C-arm. The frequency of attendance is stated in parentheses when more than 1.

Type of surgery	**Body part**	**Description**
Neuro surgery	Low back vertebrae	Hernia stenosis (n=3)
Orthopedics	Hip	Total hip prosthesis (n=10)
		Prosthesis revision
Trauma	Foot & ankle	Ankle fracture (n=2)
		External fixation foot fracture
		Arthrodesis foot
		Removal of dorsal screw
		Plate osteosynthesis tibia
	Humerus	Humerus plate insertion
		Humerus plate removal
	Hip	Hip fracture
	Hand& wrist	Zaidenberg gevascula graft
		Distal radius fracture (n=2)
		Plate fixation fracture hand
	Ulna & radius	Removal of cables from bone
	Clavicula	Clavicula fracture
		Variax plate clavicula
		Distal femure fracture
Vascular	Torso	Port-a-cath system insertion
		Jugularis catheter
	Abdominal region	Endovascular Aneurysm Repair

OR. In most surgical cases that make use of a C-arm, a laboratory technician from the radiology department is present to control the C-arm (C-arm controller). The only exception is the removal of stenosis in which case the circulator (circulating assistant) controls the C-arm.

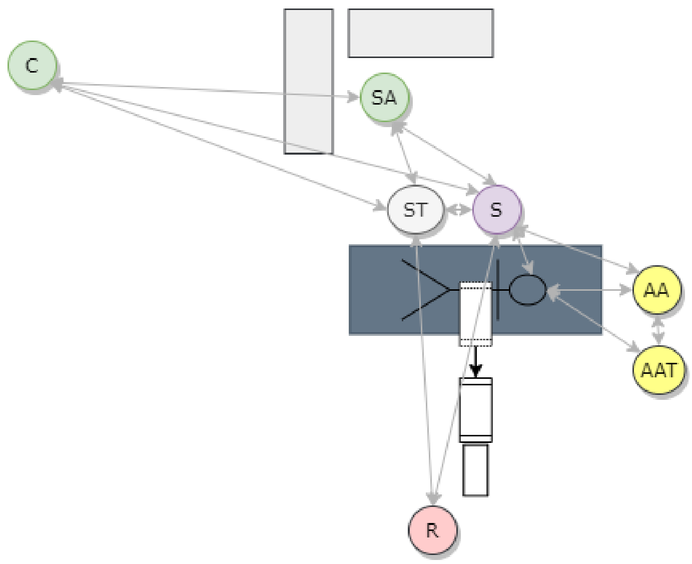

Figure 4.7: Basic OR set up showing main communication lines between staff members during surgery. The C-arm is shown next to the operating table in active and non-active position with an arrow indicating the difference. C = circulating assistant. SA = surgical assistant. ST = surgeon in training. S = surgeon. AA = anesthetics employee. AAT = anesthetics employee in training. R = C-arm controller.

Location & Movements During standard procedures, most people present in the operating room deviate little from their working area. Only the circulating assistant is walking around during the procedure, collecting instruments and implantable material for the surgical assistant. The standard staff positions for basic trauma and orthopedic surgery are visualized in Figure 4.7. When the incision is being closed, the suture is collected by the circulator, handed to the surgical assistant and after that to the surgeon. When the incision is closed, disposable materials are removed from the sterile zone by all staff members.

During the operation, the patient, surgeon, surgical assistant, other sterile observers, instruments and C-arm should all be positioned next to the operating table, in the sterile zone of the OR. Sometimes there is a lack of space and the instruments have to be moved out of the sterile zone to make way for the C-arm. When moving instrument trolleys out of the sterile zone, this makes it more difficult to guarantee the sterility of the surgical instruments. Closest to the patient are the surgeon, the surgeon in training and surgical assistant. The anesthesiologist is close to the patients head, but normally further away from the operative site. Sometimes an additional surgeon in training or medical student is present to observe.

Workload For all observed procedures, the surgeon and surgical assistant have a relatively uniform distribution of workload during the operation. The distribution of workload for other staff members varies throughout the operation and among operations. Anesthesiologists are mostly active during the beginning and end of the procedure, dealing with anesthesia for the patient. The workload for the C-arm controller during surgery is generally low with peaks when patient screening occurs. For routine procedures, these screening moments are predictable whilst for more complicated procedures they are unforeseeable. Circulating assistants are very active at the beginning and end of the procedure, preparing patient set up and removing it afterwards. During surgery, the main task is to collect and dispose materials. The workload involved with this task depends on the type of procedure. For orthopedic/trauma procedures that make use of few (temporary) implantable materials such as plates and screws, the workload for circulating assistants is relatively low. This is also the case for the C-arm controller; as the amount of implantable material decreases, the workload for the C-arm controller decreases as well.

Distancing The inverse square law implies that the dose received by operating staff can be significantly reduced by taking one or more steps back during screening (see Appendix B). The positions of staff members in the OR were evaluated during screening moments and it was observed that generally, only the surgeon and assisting surgeon (in training) are bound to standing near to the C-arm to hold the patient in the right position. In case of treatment of extremities, the hand or foot is often held by the surgeon in order to get an image from the right angle. Consequently, the hand of the surgeon is located directly under the beam during screening. Direct exposure results in a relatively high dose for the surgeons hand but due to the low tissue weighting factor of skin, the effective dose remains small (see Appendix B) (500 mSv can be received on hands before any harmful tissue reactions occur). All other staff members are not restricted in taking a step back and should do so in order to minimize exposure. However currently, no distance is being taken from the patient during screening and especially for the anesthesiology staff, C-arm controller, non-sterile surgical assistant and potential spectators, any significant received dose is unnecessary. Anesthesiologists are positioned closely to the patient but are often separated from the rest of the operating staff by a surgical cover. The anesthesiologist is mainly occupied with the state of the patient and not so much with surgical actions. Also, it was noted that there is variation between C-arm controllers in their distance to the C-arm. A cable is attached to the controller and allows them to take multiple steps back from the X-ray tube, but this is rarely being done.

Shielding Shielding from the radiation source using lead is a functional way of radiation protection (see Appendix B). Lead attenuates X-rays effectively since it has a low half value thickness; a thin layer of lead is capable of attenuating a high percentage of X-rays. Shielding is accomplished in the OR by wearing lead aprons, thyroid protection and sometimes lead glasses and/or gloves. Generally, all operating personnel present in the operating room wear lead aprons. Most lead aprons are removed when the C-arm is disabled after screening, except for the aprons worn by scrubbed staff standing in the sterile zone. During stenosis removal, the scrubbed staff does not wear a lead apron but stands behind non-scrubbed staff during moments of screening. Wearing thyroid protection is often being forgotten or neglected by staff and lead glasses are present in the hospital but never worn. Also, no lead screens are being used in the operating rooms of the RDGG. Overall, little shielding is applied in the operating rooms of the RDGG.

Experience/skills The experience of the C-arm controller has shown to be of great influence on the radiation emission needed to get a good visualization. A few inexperienced C-arm controllers were unaware of the content of the procedure and as a result, wrong body parts were screened and multiple images were of poor quality. This led to more exposures and thus the use of more radiation to get good visualization. For the insertion of a port-a-cath system, the patient (and staff) was exposed 29 times instead of the minimal amount of 5 exposures that were necessary according to the surgeon. 24 redundant exposures were caused mainly by lack of experience of the C-arm controller. It must be noted that this was an unusual situation which is not completely representative for the other procedures. Education of C-arm controllers appears to be not always sufficient; observations revealed that the working principle of the C-arm and how to minimize the radiation dose are not always fully understood.
Experience/knowledge of the C-arm controller is also one of the factors that influences communication between the surgeon and the C-arm controller (see next paragraph).

Besides experience of the C-arm controller, the surgical skills seems to be of influence on the radiation use and operating times. Observations have showed that when a surgeon in training performs surgery, this leads to longer operation times and the use of relatively more radiation. Table 4.3 shows that on 14-1-2020 (11:32), when the surgeon in training performed the operation, the operating time was relatively long and the amount of exposures is much higher than in other procedures. The DAP for this surgery performed by the surgeon in training was 2 to 3 times higher than for the other operations. These findings support the expectation that surgical experience has a significant influence on fluoroscopy use.

In the RDGG, all staff members seem to be aware of the risks of working with X-rays and the measures that are essential when minimizing exposure. They are familiar with the ALARA principle and the inverse square law. During observations, it has been noticed that the staff is trained to deal with radiation exposure, but there also regularly are medical students present in operating room who seem to be unaware of the risks of radiation exposure.

Communication Misunderstanding often occurs when instructions from the surgeon are not understood or heard by the C-arm controller. This seems correlated to a lack of experience from either the C-arm controller or surgeon (in training). The lack of understanding between staff members leads to bad quality images and consequently to unnecessary screening of the patient to obtain good visualization. Other factors that complicate communication are the design of the C-arm and noises in the OR. The big and heavy design makes it hard for the C-arm controller to move it on its own and therefore often gets helped by surgical staff. When multiple people start to move the arm at the same time, this results in overshooting of the target (see Appendix E for redesign suggestions). Also, machine sounds, people and sometimes music contribute to noise in the operating room, which makes it difficult for staff members to hear each other. The C-arm controller does not always hear instructions due to other noises and in that way delays the process. Generally, it was estimated that in trauma surgery, 1 in 5 exposures was not useful, either due to bad image quality or misalignment of the C-arm.

Staff opinion Staff members working in operating rooms of the RDGG are mainly dissatisfied about the design of the current mobile C-arm. It is regarded as a big, heavy part of the operating theatre that is hard to move around. Also, because of the size it is hard to position all necessary equipment and staff members in the sterile zone. Finally, the cables and monitors restrain the circulator in freedom of movement. Additional notes made by staff members about processes that don't concern the C-arm are listed in Appendix E.

4.2.2 C-arm

Set up When planning the mobile C-arm for trauma surgery, is difficult to predict whether the C-arm will be needed for certain procedures. The removal of plates and screws can often be achieved without fluoroscopy, but occasionally it is necessary to locate and visualize them. To prevent a situation in which the C-arm is needed but not available, it is often planned for surgery but eventually not used. Meanwhile the demand for fluoroscopy guidance is high and increasing as the aim is to perform surgery in a minimally invasive way. There are currently 8 operating rooms and 3 C-arms present in the RDGG and operations are scheduled partly based on the availability of the C-arm. Since the devices are sometimes being redundantly booked while the demand is high, the C-arm planning is currently not optimal.

Location & **Movements** The C-arm is mostly positioned at the opposite site of the surgeons working area and operated by a C-arm controller from the radiology department (see Figure 4.7). In some cases, mostly during trauma surgery concerning extremities, the surgeon is seated next to the C-arm. The position course of the C-arm throughout the procedure varies among different types of surgery:

- The C- arm is often used and in such a position that the surgeon can keep working while the C-arm is in screening-position. The device does not have to be moved to the operative site before screening. This is often the case for complicated trauma procedures concerning the hand or foot, when the surgeon is seated next to the C-arm. Endovascular procedures such as EVAR also use this approach.
- The C-arm is regularly used and the machine is in a rigid position in the sterile zone. The device is in screening position but the arm is slightly retracted, in order to provide space to the surgeon and/or surgeon in training. This can be seen in Figure 4.7. Before screening the arm is extended to the right position, which normally takes a few seconds. This set up is often preferred during hip surgery, in which case the C-arm is extended during preset moments of screening. The area of screening is determined at the beginning of the procedure based on a few images, and the C-arm is positioned in way that only extension of the arm is required to reach the area of screening. In between those moments, there is enough space for the surgeon and/or assistant to reach the operative site.

- The C-arm is set aside to be non-active and used a few times (e.g. to check the position before making incision) and in that case is moved towards the table. Positioning the C-arm usually takes 2-8 seconds. Examples of operations that use the C-arm in this way include the removal of stenosis and the removal of metal implants.

Which of these options is applied varies per operation and the surgeons preferences. For THP, the C-arm is regularly used, so the device is in a rigid position and the arm is extended before screening. For stenosis treatment the device is positioned in the sterile zone only at the beginning of the procedure, and is set aside afterwards. Besides this, the main position of the C-arm is largely dependent on whether the area of focus is reachable for operating staff members. Whether the area is reachable depends on the number of people that are involved in the operation and whether they are sitting or standing. Also, the quantity and position of instrument trolleys and the size and location of the body part that is being visualized affect the accessibility.

For trauma surgery at extremities, the anterior- posterior (AP = 0°) and lateral view (90°) of the C-arm are alternated to visualize the situation. The two angles are needed to get a good view of how screws are inserted in the bone. By alternating the angle, the screw is visible from the side (to see the depth) and in the same plane as the drill. This is important in order to notice when screws are too long to fit in the bone correctly, in which case the screw has to be removed and replaced by a shorter one. The anterior-posterior is the standard position of the C-arm at 0°, the lateral view is obtained partially by rotating the C-arm and partially by rotating the limb. Rotation of the C-arm ranged from 72° to 90° (including 75° and 80°) and the residual angle was achieved by rotating the limb.

Radiation use The patient dose can be kept as low as possible by reducing tube current or tube voltage. However, lowering the tube current and voltage can lead to low quality images which in its turn lead to the need of more images to get a good visualization. Acquiring good image quality has priority and therefore these settings are automatically set by the X-ray tube and preferably should not be adjusted. Another important factor that affects patient dose is the fluoroscopy time, which depends on the number of exposures and the duration of exposures. Fluoroscopy time can be minimized by factors such as good communication between surgeon and C-arm controller, surgical skills and a well informed C-arm controller.

The removal of spinal stenosis and total hip prostheses (THP) are routine operations. Both procedures have a clear sequence of events, and the fluoroscopy time and amount of exposures are very similar with few deviations. Fractures of the extremities on the contrary often differ per operation due to variation in fracture type and treatment. The amount of radiation deviates a lot per operation and the surgeon follows the protocol but some level of creativity is often required. The radiation use for vascular surgery is high and variable, influenced by surgeon experience and patient factors that complicate the procedure. Procedures that have a clear structure such as THP and stenosis removal can be predicted more easily and are more interesting for evaluation and optimization of radiation use.

Table 4.3: Time points of patient arrival, incision, closing and patient departure of 10 THP procedures that were observed in the Reinier de Graaf hospital. At the blank spots, no time point was registered because the end of the procedure could not be attended.

Date	**Arrival**	**Incision**	**Closed**	**Departure**	**Total time**	**Operating time**	**Exposures**	**Dose (mGy)**	**Time (sec)**	**DAP (Gy cm^2)**
31-10-2019	08:15	08:37	09:45	09:50	01:35	01:08	17	0,39	00:13	0,13
13-11-2019	08:11	08:37	09:37	09:42	01:31	01:00	46	1,87	00:22	0,61
5-12-2019	13:27	13:49					25	0,80	00:20	0,21
19-12-2019	07:57	08:28	09:15	09:21	01:24	00:47	36	0,83	00:19	0,27
19-12-2019	09:34	09:56	10:41	10:44	01:10	00:45	32	0,55	00:16	0,14
19-12-2019	10:53	11:14	11:55	12:01	01:08	00:41	22	0,38	00:11	0,12
14-1-2020	08:19	08:45	09:23	09:29	01:10	00:38	12	0,57	00:08	0,21
14-1-2020	10:09	10:23	11:04	11:09	01:00	00:41	13	0,65	00:09	0,24
14-1-2020	11:32	11:52	13:30	13:33	02:01	01:38	27	1,33	00:19	0,45
14-1-2020	13:56	14:15	14:51			00:36	13	0,46	00:10	0,14

Radiation data It was noted that the high dose received by the patient at 13-11-2019 (Table 4.3) is not in proportion to the fluoroscopy time compared to the other procedures; it is higher than would be expected. This outcome is a result of an increase of the tube current during surgery, which was needed to get good image quality. Initially, the tube current is set as low as possible and it is increased when the quality of the images turns out to be too low. Image quality can be affected by patient factors and in these cases, a higher tube current and/or voltage is needed to improve the quality.

Figure 4.8 visualizes the fluoroscopy time, number of exposures (runs), DAP and AK (dose) for observed THP, hand and foot procedures. From this distribution and the CV shown in Figure 4.9, it can be seen that THP surgery is relatively routine procedure; the fluoroscopy time is very similar among operations. However, more variability can be seen in the dose (DAP and AK) for THP procedures. Also, THP procedures are part of the hip procedures in the general data file and when comparing THP to the general hip data discussed in chapter 4.1.2. (table 4.1), it can be seen that THP procedures are not representative for hip procedures and vise versa. This illustrates how the collective C-arm data file is not specific enough to represent specific procedures. The variability of data from hand procedures is high due to the large variation in operations. Radiation use for foot surgery was less variable than for hand surgery.

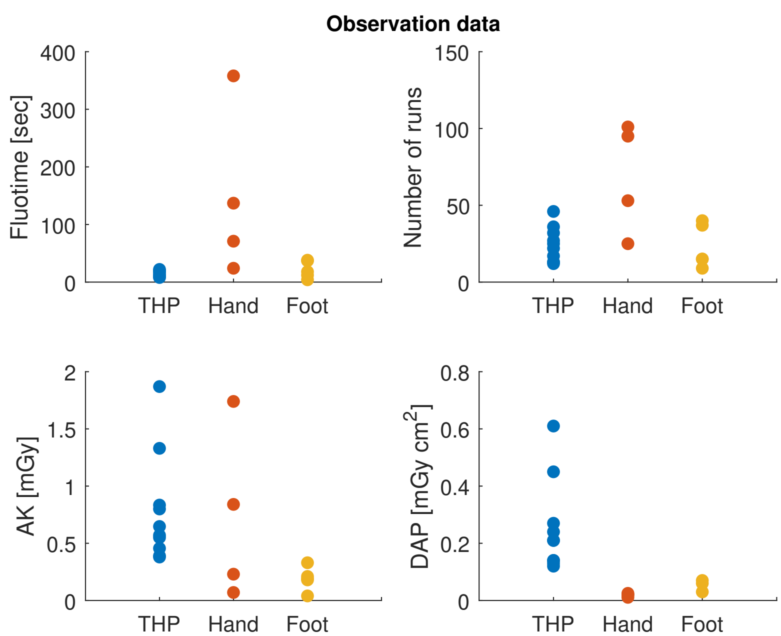

Figure 4.8: Visualization of observation data in individual value plots. Each dot represents a data point. THP (blue) has 10 data points for all variables representing 10 procedures, hand/wrist (red) has 4 data points and 6 data points represent foot/ankle (yellow) procedures.

4.2.3 Process

Time course Time points were registered for all attended procedures. The operating times of the three attended stenosis removals were 40 minutes, 43 minutes and 32 minutes. These are similar and support the statement on stenosis removal being a routine procedure. As can be seen in Table 4.3, operating times for total hip replacement surgery (THP) are also generally comparable, since the procedure requires the same sequence of actions from the operating staff. Surgery performed by the surgeon in training (14-1-2020, Table 4.3) took significantly longer than surgery performed by the surgeon, showing the influence of surgical experience on operating time.

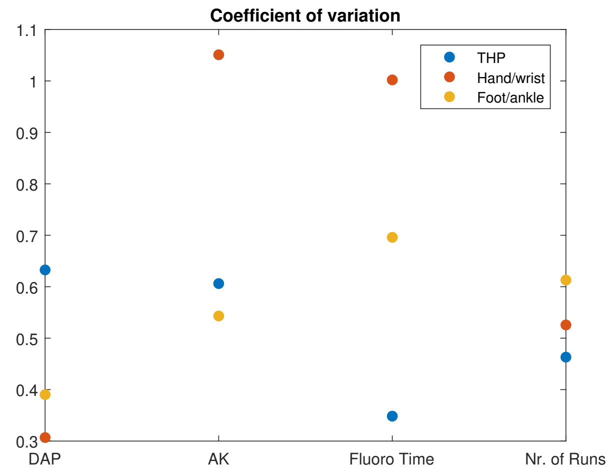

Figure 4.9: The coefficient of variation of DAP, AK, fluoroscopy time and the number of runs, calculated for hand/wrist (blue), foot/ankle (yellow) and THP procedures (red).

Patient factors Observations in the OR have shown that high BMI, bigger body parts and the use of metals automatically lead to an increase of tube current and/or voltage. The C-arm detects automatically which settings are needed in order to obtain high quality images.
In trauma and orthopedic surgery, there is a consideration between the scar size and radiation dose for the patient; if the incision is larger, visualization is easier with the naked eye so fewer fluoroscopy is needed. However the disadvantage is that a larger scar remains. It is currently accepted to slightly increase the radiation dose to get a good image while keeping the scar as small as possible, mainly because the increase in dose is neglectable compared to the difference in incision that can be made.

Delays & Complications Poor image quality resulting from incorrect tube settings can cause delays during surgery. In this case, additional images have to be made in order to get a good visualization. Besides incorrect tube settings, misalignment of the C-arm also leads to insufficient visualization. Multiple causes for misalignment were observed: firstly, misunderstanding between surgeon and C-arm controller leads to misalignment of the C-arm. Secondly, operating room lights complicate alignment of the C-arm to the surgical area. The lights in the operating room are very bright to provide clear vision for the surgeon on the area of focus. C-arms have red laser lights that indicate the aim of the X-ray bundle on the patient, but these aren't visible when operating lights shine on the same body part. This makes it harder for operating staff and C-arm controller to see the focus of the X-ray bundle, leading to confusion about the desired position of the C-arm. Thirdly, the heavy and large design of the C-arm complicates movements inside the operating room.

Another regularly occurring complication leading to delays is the absence of the right surgical instruments or implants. Waiting for the right instruments or implants shuts down OR processes and causes delays. More causes that are not C-arm related are listed in Appendix E.

4.3 DoseAware Experiments in the OR

Keeping in mind the goal of this study, the results of the previously performed experiments by medical physicists of the RDGG are interpreted. As can be seen in Table 4.4 and Figure 3.1, the anesthesiologist, C-arm controller, radiologist and surgeon receive a significant dose during the EVAR procedures (the attended EVAR procedure was appointed to be representative for EVAR procedures in general). These staff members were all standing next to the operating table or C-arm during screening. The dose received by the anesthesiologist and C-arm controller is avoidable since they don't necessarily have to be as close to the X-ray source as they are right now. This finding matches OR observations from other procedures in which these staff members were also standing close to the C-arm whilst not having to. The medical physicists hypothesized that the sterile blanket blocking the view between the operating area and anesthesiologist could give a false sense of protection against radiation. Observers and circulating assistants that were standing further away from the C-arm received a very small dose (< 1 μSv).

Table 4.4: People present in the operating room during EVAR procedure, their badge number and received dose.

Badge nr.	**Function**	**Received Dose (μSv)**	**Notes**
1	Anesthesiologist	14	
2	C-arm controller	13	
3	Radiology laboratory technician	< 1	sterile zone
4	Radiologist	16	sterile zone
5	Medtronic employee	< 1	
6	Circulating assistant	2	
7	Surgeon	17	sterile zone
8	Circulating assistant	< 1	
a	Radiology laboratory technician	-	no badge
b	Surgical assistant	-	no badge, sterile zone
c	Clinical physician	-	no badge, behind lead screen
d	Philips employee	-	no badge, behind lead screen

4.4 Discussion Observations and Data Analysis

Fewer operations could be attended than initially intended. This was partly because multiple operations with scheduled C-arm, did not use one and partly because the communication with the hospital planning staff was difficult. As a result the observation data were scarce. Because of the small sample size, boxplots and further variability research would not result in reliable conclusions and therefore, the observed procedural data were plotted individually and scanned for remarkable properties.

Data acquired from the C-arm were incomplete and not specific; not all data were saved in the collective C-arm data file and procedures were filed under general exam names that didn't specify the operation (see AppendixC). Exam names from the collective C-arm data file were appointed to be part of a procedure type such as hand, foot, hip or vascular surgery (see Table 3.1). However, radiation data for e.g. a hand or wrist operation could have been stored under a wrong exam name and thus be not included in analysis. Also, e.g. screening of underarm (see Appendix C; 'Doorlichting onderarm') was not assigned to hand/wrist surgery, whilst this would have been appropriate in some cases. However, due to the unspecific data storage a correct distinction could not be guaranteed. The received dose was not noted during neurosurgical operations (removal of stenosis) and not registered in the data file that contains radiation data from the mobile C-arm, so there were no data to be analyzed. Despite this, observation notes of neurosurgical procedures were included in the study. For future research into C-arm use in the RDGG, data from the C-arm should be stored under more specific categories.

Chapter 5

Discussion

5.1 Interpretation of results

The goal of this study was to investigate whether mobile C-arms are being optimally used, securing the safety of staff members in operating rooms of the Reinier de Graaf hospital (RDGG). Mobile C-arm use is evaluated in terms of radiation emission and radiation exposure, staff communication and procedural aspects. In order to do so, the current use has been mapped for trauma, orthopedic and vascular procedures. Radiation emission was analysed based on fluoroscopy time, the number of exposures, DAP and AK values obtained from the registered C-arm data. Radiation protection, communication and processes were analysed by observing procedures in the operating room.

Based on the evaluated C-arm data, we conclude that the radiation emission varies between different types of surgery. Compared to trauma and orthopedic surgery, vascular procedures require the emission of relatively many X-rays. For trauma and orthopedic procedures, the radiation dose is currently relatively low and thus no high risks are currently involved for the operating staff when using appropriate shielding. However despite the low emission, it is essential that everyone acts according to the ALARA principle because of the growing interest in fluoroscopy guided procedures.

Variability It has been observed that variability is high for trauma surgery. In general, but especially when little data are present, it is hard to generalize the variable data from this type of surgery. The variability also makes it difficult to optimize this procedure, since every operation has a different process flow. In the observation data, more variability can be seen in the dose (DAP and AK) for THP procedures than for trauma procedures, despite THP being a routine procedure. This can be explained by the increased amount of radiation that is needed in order to visualize a bigger body part. Due to the relatively high amounts of radiation that are being used, changes in fluoroscopy time lead to significant changes in dose. Also, the BMI of the patient has a bigger effect at the hip area than it does at extremities and a larger amount of metal is used. As a result of these three factors, the dose/AK for THP procedures is higher and the variability seems to be higher. The visualized data obtained from the C-arm file mostly support the observation data, but the variety in hand and foot surgery seemed underexposed in C-arm data due to the low emission compared to other types of procedures. Because of this gap in order of magnitude with procedures such as vascular and orthopedic surgery, the mutual differences within trauma operations were less clear in the results. This could be improved by evaluating trauma and orthopedic surgery separately from vascular surgery.

When comparing the variability of the number of exposures, fluoroscopy time, AK and DAP over all procedures, the variation is smallest for the number of exposures. This is expected since unlike the DAP and AK, the number of exposures is less affected by the duration of the fluoroscopy run, the use of metal and patient factors. The influence of patient BMI is supported by the data from THP procedure at 13-11-2019 (see Table 4.3). Here, the received dose was higher than expected when looking at the fluoroscopy time and the difference could be appointed to the high BMI of the patient. Besides this, the amount of metal varies per procedure and this variation can lead to deviating radiation doses necessary for visualization. Increasing the use of metal results in the need for a higher radiation dose to get a good visualization of the surrounding tissue. Image quality can be affected by bigger body parts, higher patient BMI and the use of metal. In these cases, a higher tube current and/or voltage is needed to increase the quality.

Comparison of surgery types Comparing individual surgery types to the remaining procedures in terms of the 4 variables has shown that especially the DAP and AK value of hand and foot surgery are very low. This is mainly due to the small body part and the small amount of metal used. The number of runs is more comparable to other operations which can be explained by the relative complexity of many hand and foot fractures. These fractures vary among patients and thus some creativity is required for treatment. Compared to the number of runs, fluoroscopy time is relatively low which could be due to the small share of moving images used by surgeons.

For vascular surgery, the number of runs is relatively low compared to fluoroscopy time, AK and DAP. This can be explained by the moving images that are made to visualize procedural actions, which are registered as one run. Fluoroscopy times are high since vascular procedures are mainly performed minimally invasive and thus fluoroscopy is the only visualization possibility. The high DAP and AK can be explained by the high fluoroscopy times and by the mostly deep body parts (the thorax) which require more radiation to image. For hip surgery, the fluoroscopy time is below average. When comparing the graph showing hip surgery versus the other procedure types to the other graphs, the high average of other procedures appears to be mainly determined by vascular surgery. The DAP and AK value for hip surgery are significantly larger than for foot and hand operations, which is accountable to the larger body part that is being screened and the larger metal implants used.

Variable correlation It has been found that fluoroscopy time, number of exposures, DAP and AK are positively correlated. DAP and AK are highly correlated as was expected based on their meaning in practice. DAP and AK both have relatively weak correlations to the number of exposures and the fluoroscopy time, which is probably because DAP and AK are influenced by multiple additional (patient) factors. Despite this, fluoroscopy time is positively correlated to AK and DAP. This is in line with expectations since an increase in screening duration leads to a proportional increase in patient dose if the same X-ray tube settings are maintained.

The positive correlation between the number of runs and fluoroscopy time was weaker than between fluoroscopy time and AK/DAP. The significant correlation can be assigned to the practical relation between the variables: more exposures lead to more fluoroscopy time and for most procedures this happens proportionally; each exposure adds a similar fluoroscopy time. Only for a few procedure types, longer runs are used in order to create moving images, which leads to a disproportionate increase in fluoroscopy time relative to the number of runs. Moving images that require varying amounts of fluoroscopy time per run, have negative effect on the correlation between the variables. The line showing correlation between fluoroscopy time and the number of runs was a bad fit due to the two point clouds in the graph. The separation in data points can be explained by differences in fluoroscopy duration per run. This variation causes a non linear relation between the number of runs and fluoroscopy time.

The findings were compared to literature: Olgar et al. measured patient and staff doses for some complex X-ray examinations. The examinations included double contrast barium enema, single contrast barium enema, barium swallow, endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangiography (PTC), and various orthopaedic surgical procedures [11]. They found poor correlation between fluoroscopy times and DAP values for barium studies and assign this to the complexity of the procedures. For ERCP and PTC the correlation was good (R^2= 0.86) [11]. These results show that the correlation between measures can vary per procedure. Due to the non specific exam names, it was not possible for this study to look at correlation between measures for specific procedures. McArthur et al. investigated patient and surgeon exposure during direct anterior total hip arthroplasty. They found DAP and fluoroscopy times comparable to other published values and a positive correlation between the two measures ($R^2 = 0.45$) [12]. This value is similar to the correlation between DAP and fluoroscopy time found in this study (R=0.65, R^2= 0.42). Literature is thus predominantly in line with the finding that fluoroscopy time is correlated to the dose received by the patient and staff and should thus be kept as low as possible.

Process Time courses and radiation data of fluoroscopy time and number of exposures support the observation based hypothesis that the removal of spinal stenosis and total hip prostheses (THP) are routine operations. Both procedures have a clear sequence of events and the fluoroscopy time and amount of exposures are very similar.

Deviations are mostly present in patient dose (AK and DAP) and can be appointed to patient factors, case specific differences and surgeon experience. Fatty tissue complicates the surgery and can cause longer operating times.

Time course data from procedures are valuable since the time that the patient is under anesthesia should be limited at all times. Also, operating times are preferably as low as possible due to financial reasons. Mapping operating times from different types of surgery can lead to better approximations for surgical planning.

(Patient) factors In this study, variation in patient dose has been appointed to differences between the body part of interest, patient factors, the use of metal and the complexity of the procedures. Within a type of procedure, patient factors that can potentially influence the radiation emission include gender, BMI and co morbidity. Based on the observations in the operating room, these factors seem to be most predictive of the procedure progress and the radiation emitted. McArthur et al. investigated the relation between patient BMI and radiation dose for total hip arthroplasty and found poor correlation[12]. However, other studies reported a strong correlation between BMI and radiation dose; Mekis ([13]) found a 176% increase in DAP for overweight patients (BMI > 30) in pelvic radiology. Also, Schueler et al. reported that a 5 cm increase of the abdomen resulted in doubling of exposure at the operator's waist [7].

Based on radiation data, it is predicted that the influence of BMI is dependent on the body part that is being screened; fluoroscopy use for the abdominal area will be more sensitive to an increase in BMI than extremities.

Tsapaki et al. found that males generally receive higher doses than woman [14]. Results from Schueler et al. raise the expectation that gender affect the radiation exposure because males are normally bigger than woman [7]. However McArthur et al. reported poor correlation between gender, age and radiation dose [12].
Despite the inconclusiveness in literature about the significance of patient characteristics, taking all factors into account could improve the quality of mapping and planning of surgery.

DoseAware experiments The experiments performed with the Philips DoseAware badges were not officially part of this study, but support findings and provide extra information for the future research proposals. The total measured received doses for staff members confirmed findings of OR observations; multiple staff members receive an unnecessary dose. The real time measurements were not useful for this study since no information about the actions at time points was available, but for future research, real time dosimetry in combination with a process report could provide interesting results.

Staff Observations showed that most staff members seem to be aware of the risks of working with radiation, however the attitude towards radiation protection should be more alert. Small actions such as wearing thyroid protection or taking a step back have large impact on radiation received by the staff members [4][5][8]. Radiation received by the circulator, C-arm controller and anesthesiologist could be approaching zero when acting more carefully.

Besides this, communication within the team can be improved, especially between operating staff and C-arm controller. In order to have better communication, the C-arm controller should be properly educated and informed about the procedure. Also, a lighter and smaller redesign of the C-arm could lead to more efficient communication.

The surgeons experience has shown to affect radiation emission. This outcome is intuitive and not necessarily something that should be changed; practice is needed in order to increase performance and high quality treatment for the patient remains more important than a (small) increase in the received dose. There is no limit to medical radiation dose because good treatment always has priority, as long as the ALARA principle is secured [4].

5.2 Limitations of the study

Due to external circumstances[1], no experiments could be performed to determine real time staff exposure as a result from patient screening. Instead, the observations and C-arm data were used to map the current fluoroscopy use in

[1]Measures concerning COVID-19 prohibited all hospital entries with exception for direct care providers. The planned experiments could therefore not be performed.

the operating room, providing starting points for future research into staff member specific radiation doses.

Mapping the current fluoroscopy use was complicated by the incompleteness of data obtained from mobile C-arms of the RDGG. Not all procedures could be found in the data base and consequently the radiation data from these procedures couldn't be linked to the observation data. The cause of this information gap is uncertain, but is most likely because the C-arm did not send the data to the general data file. Despite the incompleteness of the data, we were still able to identify starting points for further research.

Data obtained from the DoseAware experiment during the EVAR procedure were incomplete as well. The DoseAware badges were not worn by all staff members because part of the personnel was already scrubbed when the badges arrived in the OR. Because of this, radiation exposure of the surgical assistant was not registered. For future research, the radiation exposure for the surgical assistant can be estimated from the dose received by a staff member that has a similar position relative to the patient. Another, bigger limitation was the lack of information concerning the staff locations and actions during the EVAR procedure. Due to the lack of process information, the peaks in radiation use couldn't be linked to actions in the operating room. For future research, the value of the real time radiation exposure measurements increases if these values can be linked to events that took place in the operating room.

When observations took place in the operating room, staff members were aware of the goal of this research. As a result, the Hawthorne effect (knowing that they are being observed influences actions of the staff) may have affected the outcomes of observations. The performance of a surgical team changes when aware of being recorded, which decreases the representativeness of observations. For example, the surgeon was triggered by the presence of observer to inform medical students on the importance of the inverse square law.

This study investigated radio protection in the Reinier de Graaf Gasthuis. Remarks made by staff members of the RDGG implied that the RDGG is relatively strict in wearing protective wear. It appeared as if in other hospitals, thyroid protection is not available and lead aprons are only worn during procedures with high radiation dose. From this we conclude that the results from this study might not provide a sufficient representation of other hospitals in the Netherlands/Europe. Similar studies should be performed in dutch hospitals to obtain a view on the national situation.

5.3 Future Research Radiation Protection

In order to perform reliable future research into radiation exposure in the operating room, C-arm data should be stored more specifically. Radiation emission data can be linked to operation data such as the exact procedure name, body part, procedure notes and patient data. Creating a detailed data base would make the potential use of pattern recognition more accessible.

Future radiation emission experiments can be performed using an Alderson Radiation Therapy Phantom to mimic patient surgery. A disadvantage of this phantom is that it is a torso without limbs so only torso operations can be reliably simulated. Surgery on the limbs, which includes most trauma surgery, will be non representative. Other anthropomorphic phantoms can have limbs, which could make them more interesting for this research. However for both types of phantoms, working with a phantom does not reflect other specific patient characteristics such as gender, age, comorbidity and BMI.

As mentioned before, some studies have investigated the effect of patient characteristics on operation duration and radiation use. It would be interesting to perform additional research into the influences of these patient factors. A large database could be composed by registering anonymous patient factors and linking them to the radiation data.

Besides investigating the influence of patient factors on radiation dose, exposure for staff members during different phases of surgery should be further explored. The DoseAware badges developed by Philips can be useful in mapping staff exposure and investigating in practice whether staff receives only the necessary radiation dose. Hereby, the actions by staff members should be registered for all procedural stages and coupled to the individual radiation exposure of staff members. This method can be used per hospital to evaluate whether the hospital staff receives only the necessary dose during inevitable moments.

The Philips DoseAware system can also be used to validate estimations of staff dose from reported DAP values. The DAP is automatically registered for each procedure and is equal for all positions between the X-ray source and detector. The DAP can be used to calculate the entrance dose to the patient and from this entrance skin dose, the staff dose can be estimated using models that simulate the scatter from patient and operating table. Estimated values obtained from this model can be compared to the dose measured by the DoseAware badges.
A comparable study possibility is to establish the relation between DAP and the dose registered by the badges for different locations in the OR. This study assumes fixed positions of staff members in the OR and estimates the dose received at that location per period in time.

For hospitals in general, it would be valuable to measure the real time dose of staff members during different types of surgery. From these results, it can be determined whether the dose is significant and whether it is reducible, either by technological improvements or simple acts such as taking a step back.

For the Reinier de Graaf hospital specifically, the current system concerning the C-arm controllers in the OR should be revised. The C-arm controllers are often not aware of details of the operation due to a lack of experience, which complicates communication with operating staff. Also, for most observed operations the workload of the C-arm controller was relatively low and clustered at a few specific moments. Especially for routine operations such as THP, the moments of C-arm use are predetermined. We suggest to educate part of the operating assistants to operate the C-arm and create a flowchart to determine per operation whether a C-arm controller is needed to control the C-arm. If the workload of the circulating assistant, the C-arm controller or both is predicted to be high for a specific procedure, both are scheduled. Also, if possible complications or difficulties are being foreseen, both staff members will be scheduled. However in case of a low risk, routine procedure with few set screening moments and no additional patient risk factors, the circulating assistant could operate the C-arm. Stenosis removal procedures are an example of routine procedures with few screening moments, that eliminated the C-arm controller from the procedure. This would result in cost savings since one less staff member is present in the OR. Also, we predict it would lead to a decrease in radiation exposure because the assistant is more aware of the details of the procedure. However when pitching the idea during observations, some reservations existed among assisting staff mainly due to financial reasons and an increase in workload. The invoice for C-arm use including the man work is sent from the radiology department and assisting operating staff doesn't want to take on an extra task if radiology sends the invoice. We think that it is manageable to resolve this within the hospital structure.

When working on reducing radiation exposure, it should be kept in mind that there is a limit to received dose for all cases except medical exposure, due to priority for good diagnostics and treatment. Increasing dose for better treatment is (almost) always permissible. Besides this, doses received in trauma and orthopedic surgery are relatively small and some actions to reduce exposure significantly effect process flow, for example for a surgeon to take 2 steps back for each screening moment during surgery. In some cases, a consideration has to be made between process flow and the reduction of radiation exposure. Despite this, efforts should always be made to keep the dose for patient and staff as low as reasonably possible.

Additional research suggestions are presented in Appendix E.

We conclude that the C-arm is currently not optimally used in the Reinier de Graaf hospital (Delft, the Netherlands). The dose received by staff members is higher than necessary in order to provide good patient care. In order to optimize it, the number of exposures can be decreased by education of C-arm controllers and communication improvement. A redesign of the C-arm could make communicating and positioning of the C-arm easier. Also, staff awareness should lead to actions in limiting exposure by shielding and taking distance from the source. Finally, the current system concerning C-arm controller allocation to procedures should be revised. In order to enable future improvements, radiation and procedural data should be stored more specifically and continuously.

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Appendices

Appendix A

List of abbreviations

AK	Air Kerma
ALARA	As Low As Reasonably Achievable
AP	Anterior- posterior
BMI	Body Mass Index
CV	Coefficient of Variation
DAP	Dose Area Product
EVAR	Endovascular Aneurysm Repair
OR	Operating room
RDGG	Reinier de Graaf Gasthuis
Std	Standard deviation
THP	Totale Heup Prosthese (Total hip replacement)

Appendix B

Background information: C-arm working principle and radiation protection

This Appendix is largely based on the course 'Radiation Protection Officer Training for Industrial Radiography' provided by Reactor Institute Delft and the accompanying book 'Practical Radiation Protection' [4]

B.1 C-arm

Mobile C-arms are being used in operating rooms to visualize human tissues during operations. X-rays emitted by the tube penetrate through soft tissues but are attenuated by dense, mainly calcium containing tissue. This difference in permeability for X-rays is detected by the detector of the tube and is used to form images.

In the generator of the X-ray tube, a current of electrons is emitted by the cathode and attracted by an anode that carries a high positive potential. Electrons are slowed down and their track is bent by the high amount of positively charged protons in the anode material. As a result from the change in movement and the deceleration, energy is released as electromagnetic radiation in the form of photons. This radiation is Bremsstrahlung (braking radiation) and is called X-ray when emitted from an X-ray tube. The higher the amount of positively charged protons in the anode material, the stronger the braking effect and the more energetic photons are emitted. X-rays are bundled by lead boundaries and can enter the human body where they interact with the atoms in human tissue. A filter is placed between the anode and patient to filter low energetic photons. These photons have to be filtered because they are attenuated quickly inside the patient's body due to their low energy so can't pass through, but the patient does receive a dose. When the X-ray is switched off, no current is running so no dose is received by anyone.

Lead shields on the X-ray generator bundle the beam of photons to only go through the patient and as a result, significantly lower amounts of radiation directly reach the staff standing near the patient. X-rays react with atoms inside the patient in three different ways: the photo electric effect, Compton scattering and pair production. In the event of Compton scattering, which is one of the most dominant interaction types in the human body because of its tissue composition and X-ray tube settings, the photon reacts with an electron in the shell of an atom. However instead of using all its energy to emit an electron from its shell (photo electric effect), it recoils the electron and forms a new (Compton) photon which changes direction and has a lower energy. This Compton photon can, in its turn, interact with new atoms and since the photon has a new direction the interaction can be outside the patient. Therefore, even though radiation is strictly aimed at the body part of interest, it can still interact with atoms outside that area, within or outside the patient. Keeping this in mind, not only the patient receives radiation but also the people surrounding the patient. The amount of radiation received through scattering is lower than originating directly from the tube, but still significant. Scattering plays a more important role in proximal body parts than it does in extremities because there is more tissue around the body center, among which some vital organs, that can be affected by scattering.

X-rays can be dangerous for humans because of the ionizing properties of radiation. Ionizing radiation detaches an electron from its shell, hereby creating an ion. Since electrons form bonds between atoms, the presence of electrons in the shell of an atom determines the strength of bonds it has. An atom that has been affected by ionizing radiation misses an electron and therefore its bonds can break. If this atom is part of DNA, part of the helix breaks. In case of single strand breaks the DNA is easily repaired by replacing the lost base but in case of a double strand break, damaged DNA can lead to replacement by random bases or cell death. In the first case, the body replaces the lost bases by random ones, so the chance exists that wrong bases are placed. This is called a mutation and can modify the cell properties, possibly leading to a cancerous cell. The probability of the occurrence of DNA mutations increases if the received dose increases. These effects are called stochastic effects; the chance of the effects occurring increases proportionally to the received dose. In case of cell death as a response to DNA damage, harmful tissue reactions can occur after a exceeding a certain threshold dose and the severity of the effect is determined by the received dose. These reactions include e.g. redness of the skin, hair loss and cataracts. Harmful tissue reactions are deterministic effects of radiation, which depend on time of exposure, the dose and type of radiation. These effects are not chance related, they occur after a certain threshold dose. A third category called hereditary effects does not affect the person who receives the dose, but affects offspring by mutations in the genetic information of the germ cells that are responsible for reproduction. Hereditary effects are also stochastic, meaning that there is no threshold dose and the chance of effects occurring is proportional to the dose received. The absorbed dose is the dose received by the body and represents the amount of ionizations. This absorbed dose should be kept as low as reasonably possible (ALARA) which can be achieved by taking distance from the source, shielding, tuning of tube settings and minimizing fluoroscopy time.

Taking distance from the source has great influence on the dose received; the inverse square law states that the dose received decreases exponentially with the distance taken. This means that e.g. an increase in distance by a factor of 3 decreases the radiation dose by a factor of 9. This law applies to all types of radiation, however for α and β radiation, the range of the particles should be taken into account. Photons have no mass and by definition no range which means that the inverse square law always applies.

Shielding X-ray is mostly done using lead aprons. Lead attenuates the majority of X-rays, depending on the voltage of the X-ray machine and thickness of the lead. If an adequate lead apron is worn, the dose will be corrected with a lead apron correction factor of 0.2. This is a safe estimation and will in practice be closer to 0.1. Lead aprons and thyroid protectors are most frequently used and protect all vital organs and endocrine glands that are most sensitive to radiation. Additional shielding can be achieved by wearing lead glasses and gloves.

Since an X-ray tube is not a constant radioactive source as it can be switched on and off, the exposure is not constant: patient and staff are only exposed when the machine is activated. Therefore, the time in which the machine is active should be as short as possible. To optimize the screening time, e.g. good communication between the laboratory technician and surgeon is essential to ensure that no superfluous images are made.

The settings of the X-ray tube can be tuned in order to get a good image with the lowest possible dose. Multiple factors influence image quality, among which the body part that is being imaged, the BMI (body mass index) of the patient and the possible use of metal. High BMI or the use of metal reduces the image quality and consequentially the amount of radiation has to be increased. More radiation leads to a higher dose received by both the patient and the operating staff, which should always be taken into consideration [4].

B.2 Radiation dose

The dose received is presented in radiation energy per kg and the units used is Gray (Gy). The equivalent dose takes the radiation type into account; the dose is multiplied by a weight factor w_r. This weighting factor is 1 for β and γ radiation but 20 for α's. This means that the dangerous effects are 20 times as big for α radiation. α particles are heavy and have a high energy, however they are easily stopped; a piece of paper or a layer of dead skin cells is enough to shield all radiation. Therefore α's are only dangerous in case of internal contamination. Besides the type of radiation, the dose is corrected for the tissue that receives the dose. The tissue weighing factor takes into account the probability that radiation induces a type of cancer or genetic effect. As can be seen in table, the

Table B.1: The 3 radiation types and their weighing factor

Radiation type	**Weighting factor**
α	20
β	1
γ	1

Table B.2: Weighting factors of different types of body tissue. (*)Remaining tissues: Adrenals, extrathoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate , small intestine, spleen, thymus, uterus/cervix. Source: ICRP 2007

Tissue	**Wt**	Σ **Wt**
Bone-marrow (red), colon, lung, stomach, breast, remaining tissues(*)	0.12	0.72
Gonads	0.08	0.08
Bladder, oesophagus, liver, thyroid	0.04	0.16
Bone surface, brain, salivary glands, skin	0.01	0.04
Total body		1

weighting factor for the lungs and breast is nearly ten times as high as that for the brain. The effective dose takes into account both the tissue and radiation weighing factor and is thus most representative for the severity of the dose received. Both the effective and equivalent are expressed in Sv.

In an unstable nucleus of an atom, the proton/neutron ratio is off and the nucleus will decay spontaneously sooner or later, releasing energy. The atom is part of a radioactive compound that releases energy as ionizing radiation. Ionizing radiation is capable of ejecting an electron from its shell in a different atom, hereby inducing electron capture and creating an ion. The electron cloud around a nucleus will be in an unstable condition and will then emit energetic electromagnetic radiation. Radiation emitted from the electron cloud is called X radiation. X-rays are photons which have no mass, no charge and no range. They have light speed and can lose all energy in one interaction [4].

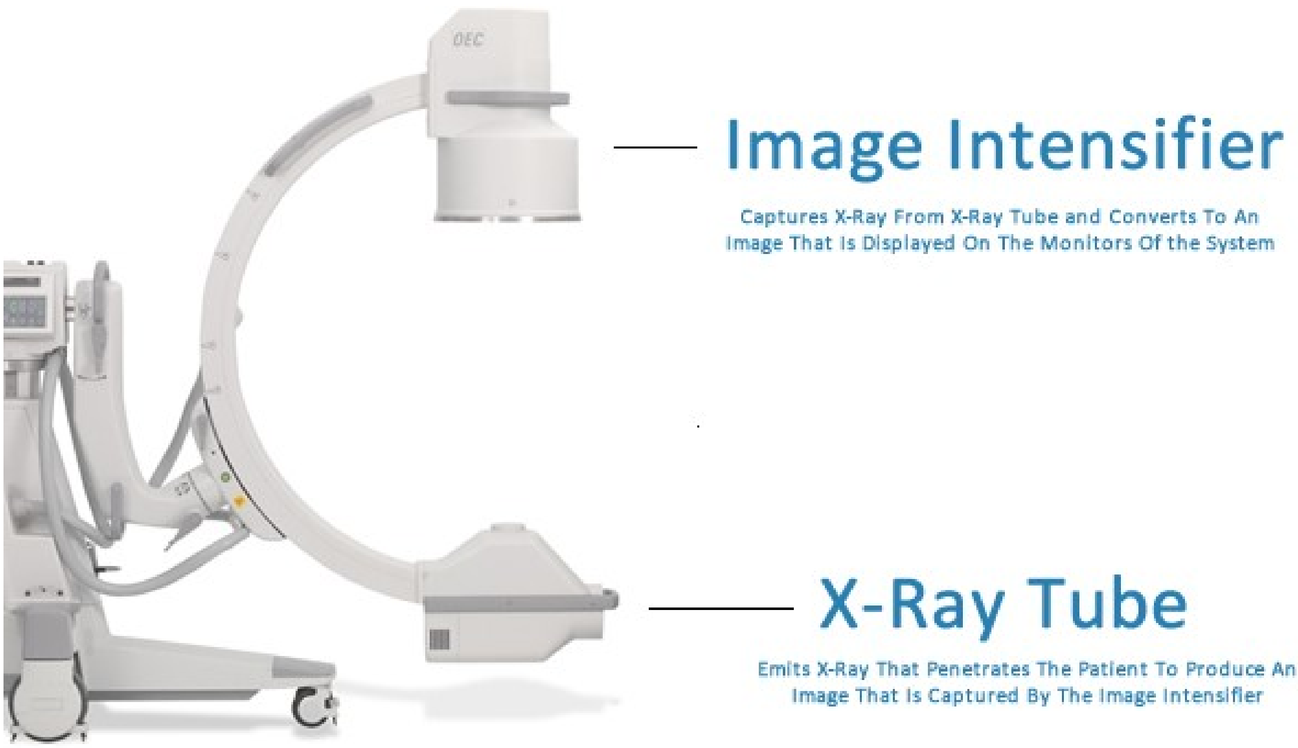

Figure B.1: Mobile C-arm used in the operating room of the RDGG. X-rays are emitted by the X-ray tube and detected by the Image Intensifier.[15]

Appendix C

Exam names C-arm Data

Table C.1: Part of the C-arm data file showing two ways for registering the same exam names.

Study Time	Exam Name
14:40	Doorlichting bekken/heup
14:07	Vasculair-Cerebraal
13:01	Doorlichting bekken/heup
10:30	Doorlichting bekken/heup
15:26	Doorlichting bekken/heup Doorlichting bekken/heup
13:47	Doorlichting pols links Doorlichting pols links
13:42	Skelet-Heup/been
13:37	Doorlichting bekken/heup

Table C.2: All Exam names present in the C-arm data file

Exam names
Arteriografie op OK
Aortastentgraft op OK
Cardio- Pacemaker
Doorlichting bekken/heup
Doorlichting bovenarm links
Doorlichting bovenarm rechts
Doorlichting bovenbeen rechts
Doorlichting bovenbeen links
Doorlichting buikoverzicht
Doorlichting elleboog links
Doorlichting elleboog rechts
Doorlichting enkel rechts
Doorlichting enkel links
Doorlichting hand rechts
Doorlichting hand links
Doorlichting knie links
Doorlichting knie rechts
Doorlichting lumbale wervelkolom
Doorlichting onderarm links
Doorlichting onderarm rechts
Doorlichting onderbeen links
Doorlichting onderbeen rechts
Doorlichting pols links
Doorlichting pols rechts
Doorlichting schouder links
Doorlichting schouder rechts
Doorlichting thorax
Doorlichting voet links
Doorlichting voet rechts
Endoscopie-ERCP
Pijn-Hoofd
PTA occlusie femoraal
PTA stenose coeliacus
Skelet-Alleen bekken
Skelet-Arm
Skelet-Heup/been
Skelet-Schedel/CWK
Skelet-Thorax
Skelet-TWK/LWK
Stent occlus. Iliacaal
Urologie- nier
Vasculair-Abdominaal
Vasculair-Arm
Vasculair-Been
Vasculair-Cerebraal

Appendix D

Highlighted Procedures

D.1 THP

During THP (total hip replacement) procedures, the femoral head is removed from the femur and replaced by a prosthesis with femoral stem that is inserted in the hollow centre of the femur. The damaged cartilage is removed from the socket using a reamer and replaced by a metal socket. In case of weak femur bones the surgeon can decide to use cement to glue the stem of the prosthesis into the hollow femur. In order to reach the hip bone, an incision is made in the thigh. During surgery, the C-arm in rigid position on brakes and the arm is extended when screening is needed. Moments of screening for this procedure are predictable and are anticipated on by the C-arm controller. In the beginning, some images are made to determine the incision location. After that, fluoroscopy is used mainly for positioning of the reamer, metal socket and the ball and stem of the implant. At the end, a few images are needed to check if everything fits well before the incision is closed. The workload of the circulator is low during this procedure; the main task is to collect prosthetic material in right size. The workload of the C-arm controller varies throughout the operation but is generally low. In between moments of screening, there is no work and it is accepted to be on their phone. In one exception, the C-arm controller helped holding tools while the surgeon was operating.

In general, operating times of THP procedures are very comparable since the same sequence of actions is performed by the staff and the risk of complications is low. Factors that have most influence on the operating time are the experience of the surgeon, the amount of fatty tissue of the patient and related to the surgeon experience is the ease with which the right prosthesis size is determined. Sometimes multiple attempts are needed to find the right size of implants, this is relatively time consuming.

Patients that undergo this type of surgery are generally 60+ years old and their BMI is average to high.

The RDGG proposed to investigate whether it is really necessary for orthopedic surgeons to wear a lead apron during hip prostheses surgery. The physical load of wearing a lead apron all day is heavy for the surgeons and there are relatively few moments of screening during this procedure. However, according to the ALARA principle (as low as reasonably achievable), the dose received by exposed workers should always be minimized within reasonable boundaries. Also, the amount of radiation that is used during THP is significant due to the fluoroscopy time, the use of metal and size of the body part. The detection of metal and larger body parts automatically results in increased dose which is necessary to acquire high quality images. Due to this significant dose and the ALARA principle, it is advised to let THP surgeons wear a lead apron at all times despite the physical load.

D.2 Trauma extremities [1]

This is a collection of trauma surgery performed on extremities treating mostly bone fractures. There is a lot of variation in treatment of these fractures, which is mainly dependent on the types of fractures and patient charac-

[1] Hand, wrist, ankle and foot are assigned to be extremities in this study.

teristics. Besides the fracture type, operating time depends on factors such as patients age, potential co morbidity and to a lesser extent BMI (low-high). Some level of creativity is often needed in the approach of the procedure and corresponding instrument use. To illustrate this with an example: an ankle fracture had to be externally fixated due to severe diabetes and the amount of fixation pins was doubled to be able to carry the patients weight. If this patient would not be diabetic, internal fixation would have been possible which would have made the operation less complex and shorter. The fluoroscopy time however would have increased due to a reduced vision. The amount of radiation used in this type of surgery is relatively low, mainly due to the small body parts and minimal influence of BMI, but varies a lot among procedures. It is difficult to establish a pattern based on observations because every fracture is slightly different. Due to this variability, the frequency of C-arm use is unpredictable. The size of incision is an indicator of the amount of fluoroscopy that will be used; bigger incisions enable better vision without screening. The C-arm is mostly not in rigid position but being driven in and out when needed. The amount of exposures can be very high for complex procedures but the received dose is relatively low because of the small body parts. The workload of the C-arm controller is very unpredictable, varying from a few seconds to a few minutes of fluoroscopy time per operation. The amount of screening needed during trauma procedures is not very predictable; the C-arm use can vary from no use at all to very frequent screening.

During this type of surgery, the circulator collects the necessary metal implants (plates and screws), following instructions from surgeon or surgeon in training who measures the desired size.

D.3 Endovascular Aneurysm Repair

EVAR is a minimally invasive procedure in which a catheter is inserted trough a small incision in the groin, and moved to the aneurysm. At the right location, a stent is placed by releasing it from the catheter. Fluoroscopy is used to follow the catheter, determine the right location for stent placement and to verify whether the stent is placed correctly. All actions are viewed on the C-arm monitor. For this procedure, the C-arm is in rigid position so it doesn't have to be moved before screening the thorax. The fluoroscopy time is very high because moving images are acquired, which together with the large body part increases the dose for the patient. Due to the complexity of the operation, multiple attempts can be needed to reach the right location and place the stent correctly. More screening will then be used to visualize the process which leads to significant variability in the patient dose. The workload for the C-arm controller is high during the entire operating time since the procedure is minimally invasive and screening is the only visualization option.

D.4 Neurosurgery: Spinal Stenosis

In surgical removal of stenosis, an incision is made into the (lower) back and part of the vertebra is removed. The C-arm is solely used to determine the location for incision and is controlled by an educated circulating assistant. The scrubbed staff does not wear protective gear during the operation because it heavy and uncomfortable and the screening time is very short. During screening moments, the scrubbed staff stands behind the circulating staff that wear a lead apron and thyroid protection. After screening, the incision is made and operation begins. Circulating staff removes the protective wear after screening.

Appendix E

Additional Observations & Suggestions

E.1 Additional Notes and Suggestions

The observations in the operating room resulted in suggestions for a better approach concerning the use of the mobile C-arm. Besides those, some additional suggestions could be made, mostly to improve efficiency of processes in and around the operating room.
One of these suggestions is based on remarks made by staff members in the operating room. Assistants (both circulating and surgical) and anesthetic employees complained about the surgeon often being late. Everyone has to wait for the surgeon to arrive to initiate the Time Out. This is partly solvable by addressing the surgeons about this issue and by making them frequently aware of the inconvenience that is caused. Besides this, a beeper could be used to automatically notify the surgeon when the patient enters the operating room. At the moment, the assisting staff calls the surgeon through a broadcast system in the entire OR department or a phone call. After this, it takes some time for the surgeon to arrive at the OR. This process can be more efficient if the surgeon knows when he/she is expected. When a beeper indicates the arrival of the patient, the surgeon can estimate the time it takes to prepare the patient for the time out.

Besides waiting for the surgeon, a frequent bottleneck is the timing between the epidural or spinal anesthesia given by the anesthesia department and arriving at the OR. The epidural or spinal anesthesia itself can take more time than expected or the anesthetic employee is late due to a busy schedule. Consequently, the operating staff is waiting for the patient to arrive. It is difficult to anticipate on this bottleneck because the situation is often unpredictable. A beeper that informs the anesthesia department when the previous procedure is being finalized (closing), clarifies the situation and makes it easier for the department to anticipate.

To further improve the efficiency of the daily OR program, a 'day start' is currently executed by some surgeons and their operating team. The goal of a day start is to go through the schedule and any possible irregularities to prevent complications during the day. Implementing this method in the entire OR department could improve overall efficiency and reduce the occurrence of unforeseen delays.

Furthermore, it was noticed that the patient is provided with information immediately after surgery, sometimes after waking up from general anesthesia. At this moment, the patient is under influence of anesthetics and not receptive for information and therefore, information provision should be avoided at this moment. An alternative is to give a written note to the patient or wait until the patient is fully aware.

Two additional suggestions have been made that concern radiation safety for the staff. The first is to design an adjustable tool that holds a hand or foot in the right angle during screening. Using this tool, the surgeon is not forced to put his or her hand under the beam to hold the body part that is being screened. The second suggestion is to put a lead screen in the operating room during operations that require little fluoroscopy. For the scarce screening moments, staff can stand behind the screen for protection against X-rays and the screen is put aside throughout the remainder of the procedure.

E.2 Redesign of the C-arm

Many suggestions have been offered that root for a redesign of the C-arm. The device is found to be too large, heavy and difficult to move. Based on observations and remarks made by staff members, a list has been made with wishes for a possible redesign:

- A smaller and lighter design. Due to the size and weight of the current design, it is difficult to move the device. The biggest constraint when designing a smaller C-arm is the processor.
- Wireless bluetooth or wifi connections to the monitor screens that display images. The wires that connect the C-arm to the monitors currently lay in the operating room and form an obstacle for the re-positioning of the C-arm or instrument trolleys.
- Color elements on the C-arm could improve communication between the surgeon and the C-arm controller. Assigning colors to parts of the C-arm makes it easier to refer to them.
- The implementation of a system that easily sets the C-arm to the $0°$ angle. A click-system would improve precision of the $0°$ angle position and make it easier to reach this position.
- Hang the C-arm from ceiling. This idea has been proposed by multiple surgeons from the RDGG. Hanging from the ceiling, the C-arm can be positioned in a similar way to the monitors. In this case, the size and weight of the processor are the biggest constraint.
- Clearer laser lights that mark the area of screening and overrule the bright OR lights. An alternative, more expensive solution is a camera that records the area of screening and shows it on a screen to the C-arm controller. In this way, the C-arm controller can see the area of screening while standing at a distance.

Appendix F

Initial research proposal

Originally, the goal of this study was to map radiation protection in the RDGG. The intention was to measure real time radiation exposure to surgical staff and compare these data to observations from the operating room. The varying tasks of different staff members appear to be of great influence on the dose received, mainly caused by differences in distance from the patient. The influence of task and position in the operating room was to be investigated by equipping staff members with real time dosimeters (DoseAware) developed by Philips (Eindhoven). Besides measurements during daily procedures, operations would be simulated by replacing the patient by a phantom and attach real time DoseAware dosimeters to movable racks instead of operating staff members. The advantage of this method is that more experiments can be performed and thus more data can be collected without exposing patients and staff to additional radiation. Both experiments, during daily procedures and simulated procedures, would take place in the operating room. Evaluation of the data obtained from these measurements combined with observation notes and C-arm radiation data would provide a founded estimation of the radiation protection in the RDGG. It would become clear whether surgical staff members receive only the necessary, unavoidable dose and act according to the ALARA principle. Data from the daily surgeries and simulated procedures could be compared to get a view on how representative simulated set ups are. However, due to external circumstances [1], it wasn't possible to perform the planned experiments in the hospital.

[1] Measures concerning COVID-19 prohibited all hospital entries with exception for direct care providers. The planned experiments could therefore not be performed.